(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification⁷: A61B

(21) International Application Number:
                                    PCT/US2003/036120

(22) International Filing Date:
                        13 November 2003 (13.11.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
    60/426,096   14 November 2002 (14.11.2002)   US

(71) Applicant (for all designated States except US): CIPHER-GEN BIOSYSTEMS, INC. [US/US]; 6611 Dumbarton Circle, Freemont, CA 94555 (US).
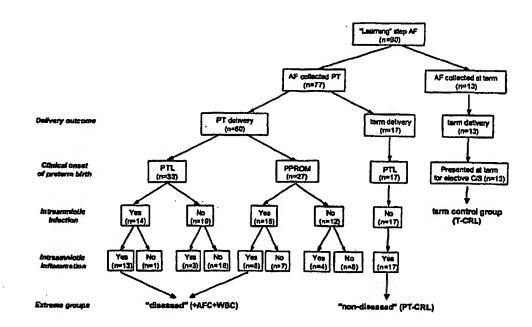
(72) Inventors; and
(75) Inventors/Applicants (for US only): BUHIMSCHI, Irina, A. [US/US]; 2728 Alisop Place, Apt. 309, Troy,

MI 48084 (US). CHRISTNER, Robert [US/US]; 2262 Parkwood Avenue, Toledo, OH 43620 (US).

(74) Agents: BENT, Stephen, A. et al.; Foley & Lardner, Washington Harbour, Suite 500, 3000 "K" Street, N.W., Washington, DC 20007-5101 (US).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: BIOMARKERS FOR INTRO-AMINIOTIC INFLAMMATION

(57) Abstract: Biomarkers have been discovered that are capable of identifying intra-amniotic inflammation. A single biomarker or combination of biomarkers can be used to qualify the risk of preterm delivery in a patient, provided that at least one of the biomarkers is a calgranulin, preferably calgranulin A or C. The result is a rapid and reliable proteomic approach to identifying intra-amniotic inflammation. In particular, the concentrations of the biomarkers correlate with the magnitude of intra-amniotic inflammation and, hence, of preterm delivery.